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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

DONALD J. TRUMP, in his official capacity as President of the United States; DEPARTMENT OF GOVERNMENT EFFICIENCY ("DOGE"); AMY GLEASON, in her official capacity as Acting Administrator of the Department of Government Efficiency; NATIONAL SCIENCE FOUNDATION;

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Case No. 3:25-cv-04737-RL

DECLARATION OF SAMUEL PIMENTEL

The Honorable Rita F. Lin

BRIAN STONE, in his official capacity as Acting Director of the National Science Foundation;
NATIONAL ENDOWMENT FOR THE HUMANITIES;
MICHAEL MCDONALD, in his official capacity as Acting Chairman of the National Endowment for the Humanities;
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY;
LEE ZELDIN, in his official capacity as Administrator of the U.S. Environmental Protection Agency;
UNITED STATES DEPARTMENT OF AGRICULTURE;
BROOKE ROLLINS, in her official capacity as Secretary of the U.S. Department of Agriculture;
AMERICORPS (a.k.a. the CORPORATION FOR NATIONAL AND COMMUNITY SERVICE);
JENNIFER BASTRESS TAHMASEBI, in her official capacity as Interim Agency Head of AmeriCorps;
UNITED STATES DEPARTMENT OF DEFENSE;
PETE HEGSETH, in his official capacity as Secretary of the U.S. Department of Defense;
UNITED STATES DEPARTMENT OF EDUCATION;
LINDA MCMAHON, in her official capacity as Secretary of the U.S. Department of Education;
UNITED STATES DEPARTMENT OF ENERGY;
CHRIS WRIGHT, in his official capacity as Secretary of Energy;
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;
ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services;
UNITED STATES CENTERS FOR DISEASE CONTROL;
MATTHEW BUZZELLI, in his official capacity as Acting Director of the Centers for Disease Control;
UNITED STATES FOOD AND DRUG ADMINISTRATION;
MARTIN A. MAKARY, in his official capacity as Commissioner of the Food and Drug Administration;
UNITED STATES NATIONAL INSTITUTES OF HEALTH;
JAYANTA BHATTACHARYA, in his official capacity as Director of the National Institutes of Health;

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INSTITUTE OF MUSEUM AND LIBRARY SERVICES;
KEITH SONDERLING, in his official capacity as Acting Director of the Institute of Museum and Library Services;
UNITED STATES DEPARTMENT OF THE INTERIOR;
DOUG BURGUM, in his official capacity as Secretary of the Interior;
UNITED STATES DEPARTMENT OF STATE;
MARCO RUBIO, in his official capacity as Secretary of the U.S. Department of State;
DEPARTMENT OF TRANSPORTATION;
SEAN DUFFY, in his official capacity as Secretary for the U.S. Department of Transportation,

Defendants.

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DECLARATION OF SAMUEL PIMENTEL

I, Samuel Pimentel, declare as follows:

1. I have personal knowledge of the facts contained in this declaration and, if called as a witness, could and would testify competently to them.

2. I am a statistician who examines causal relationships using large data sets to address problems in health services research, epidemiology, and education. I currently serve as an Assistant Professor in the Department of Statistics at the University of California, Berkeley (UCB).

3. I received a Bachelor of Science degree in mathematical and computational science from Stanford University in 2012. I received my Doctor of Philosophy in Statistics from the Wharton School, University of Pennsylvania, in 2017. Since 2017, I have worked at UCB as an Assistant Professor.

4. My research focuses on (1) developing methods for causal inference in large observational datasets from the medical and social sciences; (2) creating transparent and interpretable approaches for estimating causal effects, even in the presence of unobserved confounding variables; and (3) applying these tools to real-world problems in health services research, epidemiology, education, and public policy. In 2022, I received the National Science Foundation (NSF) CAREER award, the foundation's prestigious early-faculty award, to continue my research concerning observational study design.

5. Articles illustrative of my focus on observational studies and the medical sciences include an article on Large, Sparse Optimal Matching With Refined Covariate Balance in an Observational Study of the Health Outcomes Produced by New Surgeons, published in the Journal of the American Statistical Association 110 (510), 515-527 (2015); and an article Comparing International and United States Undergraduate Medical Education and Surgical Outcomes Using a Refined Balance Methodology, published in Annals of Surgery 265 (5), 916-922 (2017).

6. My research frequently involves collaboration with other universities and community-based health organizations. It has been supported in the past by sources that include a graduate fellowship from the Department of Defense (DoD), federal grants from the NSF and

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Food and Drug Administration (FDA), and private foundation grants.

7. A true and correct copy of my curriculum vitae is attached as Exhibit A.

Research Project & Response to FDA Solicitation of Proposals

8. In May 2023, I agreed to work as Lead Statistician for a project titled "Health and Neurodevelopmental Outcomes in Infants at Risk for Neonatal Opioid Withdrawal Syndromes: Effects of Timing and Duration of Prenatal Opioid Exposure and Postnatal Management with ESC." "ESC" stands for "Eat, Sleep, Console." The premise of our grant research was that non-pharmacological approaches to managing neonatal opioid withdrawal syndrome (NOWS) in infants, such as the use of "Eat, Sleep, Console (ESC)," hold potential to improve infant outcomes compared to opioid replacement treatment. The project planned to compare differences in outcomes between opioid replacement pharmacotherapy and non-pharmacological management in infants with NOWS. It further aimed to test the hypothesis that timing, duration, and doses of prenatal opioid exposure help predict where non-pharmacological management will be most effective.

9. The research team planned to use the Kaiser Permanente Northern California research databases as the data source. These provide high-quality data on a large patient population, allowing for the study of birth cohorts that are linked to the mothers, which provides an excellent assessment of maternal risk factors. The data includes pharmacy and clinical data from all patient encounters in Kaiser's electronic health records.

10. The project was initially proposed by Dr. Lena Sun of Columbia University Irving Medical Center (CUMC) in response to the FDA's announcement of funding opportunity FDABAA-23-00123. This opportunity was made available through an FDA Broad Agency Announcement for the Advanced Research and Development of Regulatory Science in January 2023. After our team submitted an initial white paper proposal, FDA in May 2023 invited us to submit a full proposal. A true and correct copy of FDA's invitation is attached as Exhibit B.

Grant Proposal to FDA

11. Our final grant proposal, on which I was Lead Statistician and co-investigator, encompassed seven investigators across four institutions: UCB, Columbia, Johns Hopkins School

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of Medicine, and Kaiser Permanente. Our team's expertise spanned maternal exposure analysis, fetal epidemiology, implementation science, and statistical analysis.

12. As Lead Statistician and co-investigator, my primary role in the proposed work was to lead the design and analysis of statistical comparisons between NOWS infants exhibiting exposures of interest (*e.g.*, those receiving opioid replacement pharmacotherapy, or those receiving particular prenatal doses or durations of exposure to opioids) to corresponding control groups. My role also included presenting results at internal team meetings and external scientific meetings, preparing manuscripts, and supervising a UC Berkeley graduate student who was to be supported by the award and assist me in my duties. A true and correct copy of my letter to the Principal Investigator expressing my willingness and eagerness to collaborate as a co-investigator on the proposed project is attached as Exhibit C.

13. Our research team's Grant Application contemplated a multi-campus, multi-nonprofit research collaboration that would span four years and conclude on August 31, 2027. A true and correct copy of the Application is attached as Exhibit D.

FDA's Grant Award and My Sub-Award

14. On September 28, 2023, an FDA Grants Manager transmitted to our team a Notice of FDA's award and the Grant Agreement. The Agreement indicated that we were authorized to proceed for Project Period 9/30/2023 to 9/29/2027; that the FDA would make a total estimated payment of $1,721,851; and that this amount would be disbursed in installments across each of the project's four years. A true and correct copy of the Grant Agreement is attached as Exhibit E.

15. As part of the grant funding, I was subcontracted as Lead Statistician and received $52,555 in the base year from 9/30/2023 to 9/29/2024. This funding was authorized on May 24, 2024. For the second year, I was obligated to receive $55,122.

16. My most recent subcontractor Award Summary, dated February 11, 2025, stated that FDA had obligated to me a total of $107,677 for work performed by that date and work to be performed through September 29, 2025. A true and correct copy of this Award Summary is attached as Exhibit F.

17. To date, UCB has, on paper been sub-awarded this $107,677, of which we have

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spent and invoiced $52,366. The remaining amount was to be for payment of salaries during Summer 2025.

FDA's Grant Termination

18. On March 7, 2025, a contract specialist at FDA sent to our research team an email message with subject line text: "Notice of Modification—Termination for Convenience." The entirety of the message text was:

> *Please see attached the signed unilateral modification P00003 to FDA Contract No. 75F40123C00211. Please note that the full termination of this contract is taken for the Government's convenience and is as a result of recent Presidential Executive Orders.*
>
> *Please confirm receipt of the modification P00003.*

A true and correct copy of this email is attached as Exhibit G.

19. The e-mail message had two attachments. The first attachment was a Termination Notice that stated: "The contract identified in Block 10A is hereby terminated for the convenience of the government effective 3/7/2025." It further stated that our team was to stop work "immediately." A true and correct copy of the Termination Notice is attached as Exhibit H.

20. The second attachment, titled "Amendment of Solicitation/Modification of Contract," stated: "This modification fully terminates the Contract." A true and correct copy of this amendment/modification to our contract is attached as Exhibit I.

21. On March 10, 2025, I received a notification letter from Columbia University stating that that our grant award was terminated in full. The letter instructed the research team to "immediately stop all work." A true and correct copy of the notification letter from Columbia is attached as Exhibit J.

Harms from Grant Termination

22. I and my project team have suffered immediate harm as a result of the cancellation of our FDA grant and associated subcontracts. Specifically:

a) I have been unable to complete a new set of planned analyses aimed at understanding how interactions between opioid exposure and maternal ADHD diagnoses influence a child's ADHD risk.

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b) I have spent time that would otherwise have been committed to advancing my research in public health and associated statistical methodology seeking additional funding sources.

c) To replace summer salary provided by the grant, I have agreed to teach an online introductory statistics course that will require many hours of preparation and instruction that would otherwise have been committed to research.

d) I have also been unable to offer research assistantships to graduate students for the fall semester, which will limit my research productivity.

e) The Columbia and UC Berkeley researchers on this grant have been unable to pursue our originally-scheduled series of investigator meetings, important touchpoints for sharing, framing and conceptualizing scientific findings and for planning dissemination and implementation. This has delayed our ability to progress the work completed towards publication, and has put on hold plans to pursue follow-up work (including a new proposal to conduct additional data collection for our study cohort).

f) The graduate student supported by the terminated award during fall 2024 has been unable to continue his planned dissertation work involving our data. He is currently looking for new projects and new funding to support him in the fall 2025 semester.

g) Additionally, even if we were eventually to find replacement funding for this project (a difficult proposition), they would no longer be adequate to cover our expenses. Graduate student stipends and faculty summer salary rates increase yearly according to university policy, and under any reasonable timeline by which new funding could be obtained, the originally budgeted amounts will no longer be sufficient to cover the requisite faculty and student effort.

h) In addition, attending an important conference for which grant funds had been earmarked; at which our team had committed to participate; and for which we had already made travel arrangements — the 2025 Pediatric Academic Societies meeting — required me to pull funding from other sources.

i) Unless and until our team's grant funding is restored, our team will be unable to commit to participate in additional project-relevant conferences and I will continue to be unable to present our results there.

j) These financial and professional harms are ongoing.

k) In addition, my research team's inability to complete work on solutions and treatments for prenatal opioid exposure during the country's current opioid crisis will result in the loss of value to the public.

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I declare under penalty of perjury under the laws of the State of California and the United States that the foregoing is true and correct.

Executed this 4th day of June, 2025

Signed by:
Samuel Pimentel
9936345A35CC452...

Samuel Pimentel

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